RESPONSE UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92322

Application No.: 10/562,011

REMARKS

Initially, Applicant thanks the Examiner for the courtesy of a telephone conversation on April 30, 2009, where the Examiner acknowledged that the Office Action Summary page (form PTOL-326) of the Office Action of November 3, 2008, was incorrectly marked as Final and that the Office Action is actually Non-Final. Therefore, Applicant respectfully submits that the present Response under 37 C.F.R. § 1.111 is both proper and fully responsive. A Statement of

Claims 1 and 2 are all the claims pending in the present Application. Claims 1 and 2 have been rejected.

Substance of Interview is being concurrently filed herewith.

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tanaka et al. (Cancer Letters, Vol. 172, pages 119-126) ("Tanaka"), in view of Fan et al., editors ("Mouse Skin Tumor Assay", 1996, Toxicology and Risk Assessment: Principles, Methods, and Applications, pages 124-127) ("Fan").

Applicant respectfully traverses this rejection for the following reasons.

As acknowledged by the Examiner, Tanaka does not teach or suggest the use of the instantly claimed compound for the treatment of lung tumorigenesis as recited in Claim 1 of the present Application or its oral administration as recited in Claim 2. See page 3, second full paragraph of the Office Action.

Fan discloses that:

"There also appears to be some correlation between the mouse skin tumor assay and the mouse lung adenoma assay. That is, the lowest dose administered systemically that elicits a positive carcinogenic response appears to be similar with both assays, but this requires further study

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(Pereira, 1982a)." See page 127, 3rd full paragraph of Fan, emphasis added.

Thus, it can be appreciated that while this disclosure may suggest a correlation regarding "the lowest dose administered systemically that elicits a positive carcinogenic response", it fails to suggest the correlation on anti-tumor promoting activity between the mouse skin tumor assay and the mouse lung adenoma assay. In any event, its conclusion is telling - it ends with such a phrase as "but this requires further study".

In fact, Fan discloses that: "Data are not yet adequate to correlate the results of the mouse skin tumor assay with results of lifetime cancer studies in animals and humans." See page 127, third full paragraph of Fan.

Furthermore, Fan et al. discloses that:

"A limitation of this assay is that the topical route may prevent systemic absorption of chemicals that require metabolic activation in other organ systems for carcinogenic activity to occur." See page 127, second full paragraph of Fan.

This excerpt suggests that there are at least two factors, such as absorption and metabolic activation, for carcinogenic activity to occur, which may cause differences between anti-tumor promoting activity on the skin versus those on the lung.

Thus, Applicant respectfully submits that from the teachings of Tanaka and Fan, one of ordinary skill in the art would have been motivated to arrive at the present claimed invention with a reasonable expectation of success.

Accordingly, withdrawal of this rejection is requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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